RIVERPOINT MEDICAL

MAY 2 3 2012

510(k) Summary

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Douglas Rowley (503) 517-8001
Date of Preparation:	February 14, 2012

Device Names

Trade Names:	PGLA: Vilet Fast Absorbing PGLA: Vilet Quick
Common Names:	Absorbable Surgical Sutures: PGLA
Classification Names:	General and Plastic Surgery Devices

Device Classification

FDA Class:	2
Product Classification:	
1. Vilet:	878.4493, Absorbable poly(glycolide/l-lactide) surgical suture
2. Vilet Quick:	878.4493, Absorbable poly(glycolide/l-lactide) surgical suture
Codes:	
1. Vilet:	GAM
2. Vilet Quick:	GAM
Classification Panel:	All: Class II (special controls); General and Plastic Surgery

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Predicate Devices (applicable 510(k) number listed):

1. Ethicon® Vicryl® K022269
2. Ethicon® Vicryl Rapide®: K033746

Special Controls

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

Device Description

Riverpoint Medical PGLA absorbable surgical sutures (Vilet and Vilet Quick) are medical devices used to secure tissues together or create wound closures during a surgical procedure or after an injury. Vilet and Vilet Quick sutures are multifilament, and are composed of braided strands of Polyglycolic-Lactic Acid (PGLA) coated with Poly(glycolide-co-L-lactide) and Calcium Stearate attached to a standard medical grade suture needle as applicable (sutures can be provided without needles as well). Available Suture sizes will be standard according to USP 32 requirements (8/0 through 3, depending on suture type).

Intended Uses

Vilet: Vilet (PGLA) surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.
Vilet suture is provided sterile as a single use device.

Vilet Quick: Vilet Quick (fast absorbing PGLA) surgical suture is indicated for use in superficial soft tissue approximation of the skin and mucosa, where only short-term wound support (7-10 days) is required, but not for use in ligation, ophthalmic, cardiovascular or neurological procedures.
Vilet Quick suture is provided sterile as a single use device.

Safety and Effectiveness

Each variety of absorbable suture has been designed and manufactured to be substantially equivalent to the predicate devices listed for safety and effectiveness. Materials used were selected based on known biocompatibility and established histories of use in the medical device industry for implantable devices, and are identical or substantially equivalent to the materials used in the predicate devices listed. Riverpoint Medical Vilet and Vilet Quick PGLA absorbable sutures have been designed to meet the requirements for diameter, tensile strength, and needle attachment strength

as specified within USP 32 unless stated otherwise on labeling. Testing is performed on each lot of product to verify that requirements have been met prior to release.

Technological Characteristics

The Riverpoint Vilet and Vilet Quick PGLA sutures within this submission have substantially equivalent technological characteristics as the predicate devices listed. As with the predicate devices, Riverpoint Vilet and Vilet Quick PGLA sutures are braided, coated, synthetic absorbable surgical sutures. Riverpoint Vilet and Vilet Quick PGLA sutures are provided sterile for one-time use only, and meet USP requirements unless stated otherwise within labeling.

Performance Data

Per FDA's *Special Control Guidance Document: Surgical Sutures,* performance testing, including mechanical testing in accordance to USP for synthetic absorbable suture, biocompatibility testing in accordance to ISO 10993-1, and *in-vitro* as well as *in-vivo* resorption testing has been performed to further ensure substantial equivalence with the predicate devices listed. All testing performed has demonstrated that Riverpoint's Vilet and Vilet Quick PGLA sutures meet current performance requirements for synthetic absorbable braided surgical sutures unless otherwise labeled, and that they are substantially equivalent to the applicable predicate devices.

Conclusion

Based on the information provided within this 510(k) submission, Riverpoint Medical concludes that the proposed suture products are substantially equivalent to the predicate devices listed according to the requirements of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 23 2012

Riverpointe Medical
% Mr. Doug Rowley
825 NE 25th Avenue
Portland, Oregon 97232

Re: K120556
Trade/Device Name: Vilet Vilet Quick
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly (glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: May 10 , 2012
Received: May 16, 2012

Dear Mr. Doug Rowley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Polyglycolic-Lactic Acid (PGLA) Absorbable Surgical Suture

Trade Name: Vilet

Indications for Use:

PGLA surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.
PGLA suture is provided sterile as a single use device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kraus for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120556

RIVERPOINT MEDICAL

Indications for Use Statement

510(k) Number: Unknown at this time

Device Name: Fast Absorbing Polyglycolic-Lactic Acid (PGLA Quick) Absorbable Surgical Suture

Trade Name: Vilet Quick

Indications for Use:

Fast absorbing PGLA surgical suture is indicated for use in superficial soft tissue approximation of the skin and mucosa where only short-term wound support (7-10 days) is required, but not for use in ligation, ophthalmic, cardiovascular or neurological procedures.
PGLA Quick suture is provided sterile as a single use device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kanne for MSM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120556